



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

AUG 11 1999

5654 '99 AUG 12 P1:44

The Honorable William F. Goodling  
House of Representatives  
Washington, D.C. 20515-3819

Dear Mr. Goodling:

Thank you for your letter of April 19, 1999, on behalf of, Mr. Kenneth A. Potter of Thomasville, Pennsylvania, concerning olestra, a substitute for conventional fats developed by the Procter & Gamble Company.

Olestra was approved by the Food and Drug Administration (FDA or the Agency) for use in savory snacks after careful review and consideration. We have enclosed a copy of the final rule published in the Federal Register on January 30, 1996, as well as other materials that may be useful to you.

As discussed in detail in the final rule, FDA determined that use of olestra in savory snacks is safe. This decision is based on thorough review of more than 150,000 pages of data on olestra, drawn from more than 150 studies. In addition, prior to approving olestra, FDA sought advice from independent outside experts, both in direct consultations with individual experts and through its Food Advisory Committee (FAC). A special working group of the FAC met in November 1995 to review and discuss the safety questions regarding olestra.

At this FAC working group meeting, Procter & Gamble, FDA's Center for Food Safety and Applied Nutrition, and interested members of the public presented their opinions and evaluations of the data. The working group considered four areas: Olestra's chemistry and consumption; toxicology and potential interference with drug absorption; gastrointestinal (GI) effects and labeling; and nutritional effects, including effects on fat-soluble vitamins and carotenoids. The large majority of the working group agreed that there is reasonable certainty of no harm from olestra's use in savory snacks. Following the working group meeting, the FAC held a public meeting to discuss the working group's conclusions and a large majority of the FAC concurred with the working group's findings. In reaching the decision to approve the use of olestra for pre-packaged savory snacks, FDA carefully considered the potential effects olestra might have on the absorption of nutrients.

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Nutrition studies in animals and humans were reviewed and evaluated by FDA experts and experts from outside the Agency. The evidence showed that olestra can reduce the absorption of fat-soluble nutrients (vitamins A, D, E, and K) when those nutrients are consumed with a snack made with olestra. These studies also show that such loss is readily compensated when appropriate amounts of these vitamins are added to the food. Thus, FDA's regulation requires compensation with these vitamins in amounts that will assure no decrease in vitamin intake, even if snacks are consumed with all meals, while also not contributing to overcompensation of these vitamins.

With respect to the potential effect of olestra on the GI tract, FDA concluded that the effects seen in controlled studies under conditions of high consumption do not represent significant adverse health consequences. Consumption of many foods can be associated with GI effects under some conditions. While FDA has concluded that there are no direct safety concerns with respect to olestra's potential effect on the GI tract, FDA also concluded that if a consumer experiences a GI effect from eating savory snacks containing olestra, the consumer should have access to information that will help him or her associate olestra with such GI effects. Consequently, FDA required specific labeling on foods containing olestra:

"This Product Contains Olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added."

A copy of Title 21, Code of Federal Regulations (CFR) Section 172.867, the regulation pertaining to olestra, is enclosed for further information.

As stated in FDA's overall conclusions in the final rule (pages 3167-3169), and as a condition of approval, Procter & Gamble agreed to conduct studies to monitor patterns of olestra consumption as well as effects of olestra consumption. In the January 30, 1996 rule, FDA announced that a review of these additional studies would be conducted in a public meeting of the FAC within 30 months. This meeting of the FAC took place June 15-17, 1998.

The transcripts of the June 1998 FAC meeting are now available at the FDA's Dockets Management Branch and may be accessed on FDA's website (<http://www.fda.gov>). It should be noted that the recommendations of an advisory committee are not binding on FDA, although the Agency carefully considers a committee's advice.

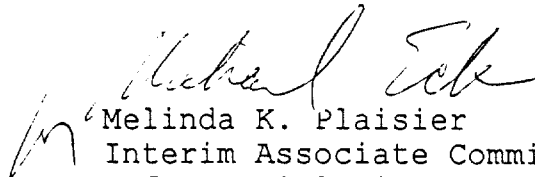
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At the June 1998 meeting, the olestra advisory committee members generally agreed that there were no new data or other information that raised significant new public health concerns. There was considerable discussion on the subject of the label, with a range of views being expressed. For those members who thought the label should be retained, the members advised that FDA should modify the statement to increase consumer understanding of it. The advisory committee encouraged Procter & Gamble and FDA to continue monitoring the product over a longer period of time.

We are forwarding a copy of your constituent's correspondence to two open dockets at FDA so that it will be considered as part of the record for any further proceedings in this matter. The dockets are #87F-0179, the original docket for the rulemaking on olestra, and #98F-0418, the docket for a citizen's petition pending with the Agency filed by Citizens for Science in the Public Interest (CSPI). The CSPI petition proposes rulemaking to prevent products containing olestra and other partially or totally indigestible fats from making a "Fat-Free" or "Low-Fat" claim.

We appreciate your interest and trust this information responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to contact us.

Sincerely,

  
Melinda K. Plaisier  
Interim Associate Commissioner  
for Legislation

5 Enclosures

"Federal Register, dated January 30, 1996"

"HHS News, dated January 24, 1996"

"FDA Consumer, dated March 1996: "Healthful Snacks  
for the Chip & Dip Crowd"

"FDA Consumer, dated July 1996: "Taking the Fat  
Out of Food"

"21 CFR 172.867"

cc: Dockets Management Branch  
(Docket No. 87F-0179)  
(Docket No. 98F-0418)

BILL GOODLING  
19TH DISTRICT, PENNSYLVANIA

CHAIRMAN  
COMMITTEE ON EDUCATION AND  
THE WORKFORCE

COMMITTEE ON  
INTERNATIONAL RELATIONS

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**Congress of the United States**  
**House of Representatives**  
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44 FREDERICK STREET  
HANOVER, PA 17331-3598

April 19, 1999

Food and Drug Administration  
Office of Legislative Affairs  
5600 Fishers Lane  
Rockville, Maryland 20857-0001

Dear Sir:

The attached communication sent to me by Mr. Kenneth Potter has been respectfully referred to you for your review, consideration, and comment.

I ask that you kindly return the enclosed correspondence to Greg Englert of my staff.

Thank you in advance for your assistance.

Sincerely,

BILL GOODLING  
Member of Congress

WFG/ge

No 99-2776



MARTIN'S POTATO CHIPS INC. P.O. BOX 28 • THOMASVILLE, PA 17364  
(717) 792-3565 • (800) 272-4477  
FAX (717) 792-4906

March 31, 1999

Representative William Goodling  
House of Representatives  
2263 Rayburn House Office Building  
Washington, DC 20515

APR 07 REC'D

Dear Bill:

I think you have ~~eaten~~ eaten enough of my chips to know that I make a quality product. If you happen to have forgotten how delicious they are, please stop out, and I will refresh your taste buds. Or if you prefer, I will gladly send a carton to your Washington office.

I am writing you about a serious problem that has arisen in the Snack Industry, regarding the fake fat called olestra (Olean). For reasons which defy logic, the Food and Drug Administration and the Federal Trade Commission approved the use of olestra for use in potato chips and other salty snack foods, despite the fact that its side effects were known—gastrointestinal disorders in some people, and the fact that it inhibits the body's ability to absorb certain nutrients.

Not only is olestra a disservice to the consumer; but also, to the company that tries to compete fairly. The FDA and FTC are permitting companies to use the term "fat free" on chips made with olestra, even though those chips are *full* of fat. The fat content in olestra chips is equal in quantity to any standard chip, mine included, so the label is totally misleading. Olestra passes through the body without absorbing; but at the same time, prevents the absorption of some nutritious foods. How can a company that honestly labels its products compete with one that deceives the customer, deliberately? Their subtle claim that the product is healthful is a betrayal to the customer and to the industry.

Bill, we need your help. Would you (a) urge the FTC ~~under the Federal Trade Commission Act~~ for olestra products, and to require that all ads for those ~~products include the FDA warning~~ stating "may cause abdominal cramping and loose stools"; (b) urge the FDA to ~~ban the terms "fat free" and "low fat" on~~ olestra products, and to require that the required label notice indicate ~~that~~ olestra may cause severe symptoms including diarrhea, and that the notice be printed in a visible spot on the front of packages (e.g., one third down from the top); (c) require that the FDA commission an *independent* study of the potential health consequences of olestra. (It appears that the FDA bureaucrats are simply defending a poor decision they made in 1996).

To me, nothing is more unthinkable than to produce a product that is injurious to my customers. Further, I do not want the public to ultimately look at the snack industry with the same scorn as they view the tobacco industry, because of this problem of deceitful advertising by companies using olestra. I look forward to your response.

Sincerely,

Kenneth A. Potter, President

APR 07 1999  
U.S. DEPARTMENT OF JUSTICE  
FEDERAL TRADE COMMISSION  
WASHINGTON, D.C. 20540

## CROSS FILE SHEET

File Number: 87F\0197/OB129

See File Number: 98P\0418/C1